REMARKS

Claims 1 and 11 are pending in the application. Claims 2-10, and 12-20 have been withdrawn from consideration. The specification has been amended to recite reference to SEQ ID NOS 11 and 12. Claims 1 and 11 have been amended. It is believed that no new matter is added by this amendment. Support for the amendment to claim 1 can be found at least on page page 21, lines 17-20.

Objection

The specification is objected to under 37 C.F.R 1.821 for the recitation of "CYGG" on page 28, line 27 and page 29, line 9 and the recitation of "LXXC" on page 49, line 29 and page 51, line 18. In particular, the Examiner asserts that the identified sequences must be identified by a SEQ ID Number in the specification as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). Applicants have amended the specification to include identification of the amino acid sequences by a SEQ ID number. Applicants believe this objection has been overcome and respectfully request its withdrawal.

Objection

Claim 11 is objected to for being dependent from a rejected claim. Applicants have amended claim 11 to be written in independent form. Support for this amendment can be found in original claim 1 and throughout the specification. Applicants believe this objection has been overcome and respectfully request its withdrawal.

Rejection Under 35 U.S.C. § 103

1. Claim 1 is rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sampson et al., U.S. Patent No. 6,217,884 in view of Tam (*In: Peptide Antigens: A practical Approach* (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, 1993, p83-90) or Huang et al. (*Mol. Immunol.* 31:1191-1199, 1994) and Harlow et al. (*In: Antibodies: A Laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988).

Applicants respectfully traverse this rejection. Applicants point out that the present application and Sampson et al. were both subject to an obligation of assignment to the same entity at the time the present invention was made. Therefore, over Sampson et al., U.S. Patent No. 6,217,884 does not qualify as art under 35 U.S.C. § 103(c). Applicants submit herewith, a separate statement indicating the obligation of assignment at the time the present invention was made. Additionally, neither Tam nor Huang et al., nor Harlow et al., alone or in combination teach or suggest all the limitations of the claims. Therefore, applicants respectfully request withdrawal of the rejection, as the combination of the remaining cited references fail to teach or suggest each element of the claimed invention.

2. Claim 1 is rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Nuijens et al., WO 9117258 in view of Tam (*In: Peptide Antigens: A practical Approach* (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, 1993, p83-90) or Huang et al. (*Mol. Immunol.* 31:1191-1199, 1994) and Harlow et al. (*In: Antibodies: A Laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988).

Applicants respectfully traverse this rejection. As the Examiner is no doubt aware, to establish a prima facie case of obvious, the Examiner must establish that there is some suggestion or motivation to make the combination either taught in the art or in the knowledge generally available in the art, there must be a reasonable expectation of success, and the art must teach or suggest all the claim limitations. In responding to Applicants previous arguments, the Examiner has made a critical error in failing to apply meaning to the term "immunospecifically

binds." The significant meaning of this term is also not addressed in the present office action. That is, the term "immunospecifically binds," which is synonymous with the terms "immunospecific binding" and "immunospecific," has a very clear art-recognized definition as an antibody which does not bind unrelated proteins. Evidence of this meaning can be seen from the description of the anti-human kappa light chain monoclonal antibody from the Biomeda Corporation (Exhibit A) and from the definition of "immunospecific conjugate" and the converse term "non-immunospecific factor" in U.S. Patent No. 4,925,788 column 3, lines 48-54 (Exhibit B). Based on this art understood definition, a peptide, which binds two different antibodies which were raised against two unrelated molecules, does not, by definition, immunopsecifcally bind either antibody, no matter how strongly it is bound. The Examiner contends that the antibody of Nuijens et al. which binds the sequence disclosed in Nuijens et al. on page 14, line 12 under Example II would bind immunospecifically to PsaA. Moreover, the Examiner states that "since the recited peptide or protein is not identified by one or more structural limitations, it encompasses Nuijen's peptide. Applicants respectfully point out that to find obviousness all limitations must be provided for in the cited combination of art. The Examiner can not ignore a limitation simply because the limitation is functional. In fact, as noted above, any antibody which does bind Factor XII as described in Nuijens et al., and also binds PsaA as disclosed herein, would by definition not immunospecificallly bind a monoclonal antibody that immunospecifically binds to PsaA. Thus, Nuijens et al. does not disclose "[a]n isolated peptide that immunospecifically binds to a monoclonal antibody that immunospecifically binds to *Streptococcus pneumoniae* pneumococcal surface adhesion A protein (PsaA)." Moreover, neither Tam nor Huang et al. can make up for the deficiency of Nuijens et al. Therefore, as no combination of Nuijens et al., Huang et al., and Tam can provide all the limitations in the claim, the claim is not obvious over the cited art. For this reason alone applicants believe the rejection to be overcome and respectfully request the rejection be withdrawn.

Furthermore, there is no motivation to modify the peptides of Nuijens et al. to meet the limitation that the peptide immunospecifically binds PsaA. The Examiner contends that

"nothing in claim 1 requires the claimed peptide to be smaller in size than Nuijens's about 12 amino acid-long peptide." The Examiner further states that "[t]here is no need for Nuijens et al. to provide any suggestion or motivation to modify the peptide disclosed in Nuijens et al. to 'arrive at SEQ ID NO: 10 [or SEQ ID NO: 6],' because claim 1 does not include that limitation." On these points the Examiner is incorrect. Claim 1 as previously written and as amended requires that the isolated peptide immunospecifically binds to a monoclonal antibody to PsaA. The unmodified peptides disclosed in Nuijens would not be immunospecific as discussed above, for they would also bind antibodies to Factor XII. A peptide that binds an antibody for Factor XII and also happens to bind an antibody to PsaA, is not a peptide that immunospecifically binds to a PsaA monoclonal antibody. Thus, in order to produce peptides that immunospecifically bind a monoclonal antibody that immunospecifically binds to PsaA, the peptides of Nuijens must be modified to only bind the anti-PsaA antibody of the claim. There is absolutely no motivation in Nuijens to make such a modification.

Moreover, if the peptides of Nuijens et al. are modified, the modification would render the peptides unsatisfactory for any use taught or suggested in Nuijens et al., that is, as a target for binding an antibody against the larger peptide (Factor XII). An unworkable motivation cannot be the basis for an obviousness rejection. Specifically, as noted in the MPEP 2143.01 "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2. 900, 221 USPQ 1125 (Fed. Cir. 1984)." For this reason alone applicants believe the rejection is overcome and respectfully request its withdrawal.

Additionally, the Examiner states that an epitope of six amino acids is sufficient in size to generate an antibody according to Harlow. As antibodies bind tertiary structures, removing peptides from a sequence could effectively change the folding pattern and thus the target for the antibody. There is no indication that the smaller peptide (i.e., SEQ ID NO: 10) would be suitable as a target for an antibody as proposed by Nuijens et al. Thus, such a modification is not suggested by any motivation in Nuijens et al. or the combination with unrelated art. Moreover,

there is no suggestion anywhere in any of the cited art that the peptides of Nuijens et al. could be improved by truncating the peptides and then modifying the peptide to become a multiple antigen peptide. Thus, the combination does not render obvious the multiple antigenic peptide of claim 1. Furthermore, as discussed above, neither Tam nor Huang et al., nor Harlow et al., alone or in combination teach or suggest all the limitations of the claims. Applicants believe the rejection to be overcome and respectfully request its withdrawal.

Lastly, the cited art and the art of the present application must be analogous art. As stated previously, it is clear from MPEP 2145, "a prior art reference is analogous if the reference is in the field of the applicant's endeavor or, if not, the reference is reasonably pertinent to the particular problem with which the endeavor was concerned." *In re Oetiker* 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir 1992)." The Examiner's characterization of Applicants remarks regarding the peptides of Nuijens et al. and the peptides disclosed in the present application is at best incorrect and at worst deceptive. Specifically, applicants have stated that one of skill in the art of *Streptococcus pneumoniae* would not be one of skill in the art of Factor XII, a clotting factor in humans. The Examiner has taken applicants statement that "[t]he Examiner is attempting to equate the two different [areas of] art because both involve peptides," and use this as admission that Applicants believe the correct area of art is "peptides." However, nothing could be further from the truth. Indeed, Applicants indicated in the very next sentence that such a characterization "is equivalent to stating that all art involving peptides is the same." Applicants went on to state that "Applicants fail to see how art relating to Factor XII could possibly be considered within the field of the endeavor of the present claims or pertinent to the problem of pneumococcal infections." These statements are patently inconsistent with the asserted admission. The Examiner seems to be saying that because one is of skill in the art of art of protecting against pneumococcal infections, one is skilled in the art of human blood clotting. If so, would it also be the Examiner's position that the discovery of a HIV-specific 15 amino acid lone immunodominant T-cell epitope would be obvious if it overlapped with 6 amino acids from a random peptide from an epidermal protein of a flat worm? Clearly not all art involving

peptides is analogous. Here, the Examiner purports that the Nuijens et al. renders the present claim obvious due to a six amino acid overlap between the peptides of Nuijens et al. (directed towards human blood clotting factors) and SEQ ID NOs: 6 and 10 of the present application (protecting against pneumococcal infections) and that the art is analogous because both are peptides. Applicants maintain that the art is not analogous to the present claim, applicants believe that the rejection is improper and respectfully request its withdrawal.

Pursuant to the above remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of the application to issue.

No fee is believed to be due at this time; however, the Commissioner is hereby authorized to charge any additional amount or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Gwendolyn D. Spratt
Reg. No. 36,016

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
404/688-0770
404/688-9880 (fax)

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Gwendolyn D. Spratt — 9-9-04

Gwendolyn D. Spratt — Date

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- **Primary Antibodies**
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Monoclonal Mouse Anti-Human Kappa Light Chain - Prediluted

Catalog #:
021D

Size:
5 ml

Description:
Monoclonal Mouse Anti-Human Kappa Light Chain

Clone:
KP-53

Isotype:
IgG1

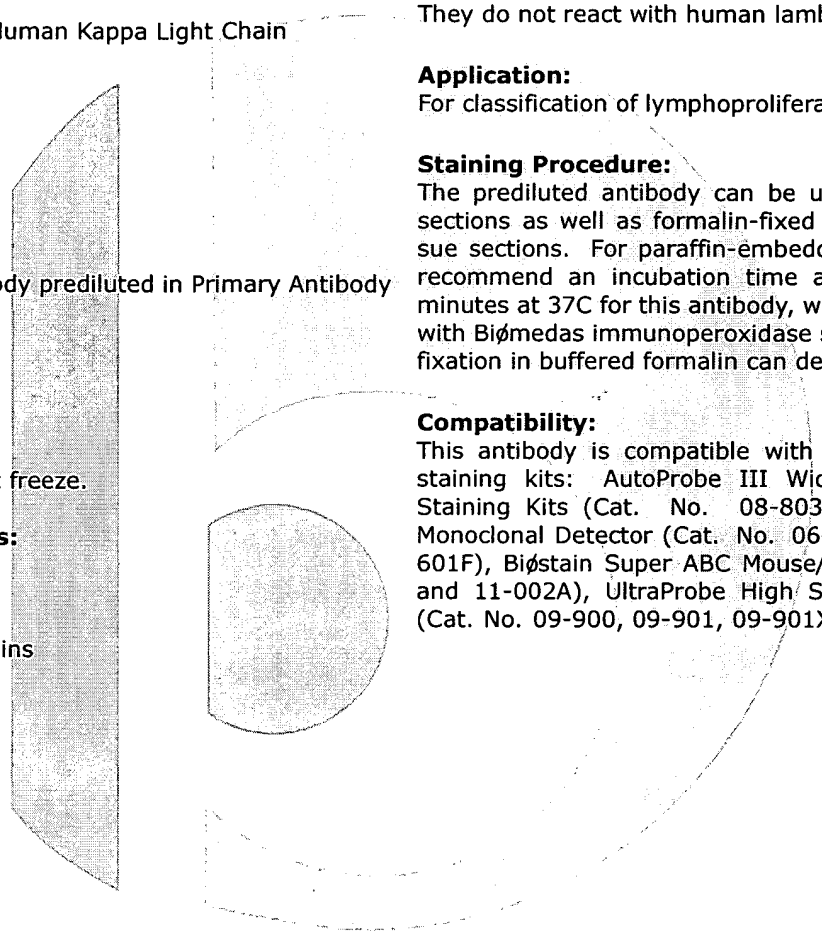
Presentation:
Mouse monoclonal antibody prediluted in Primary Antibody Diluting Buffer pH 7.6.

Host:
Mouse

Storage:
Refrigerate at 4C. Do not freeze.

Aliquoting Instructions:
Not applicable

Immunogen:
Bence Jones Kappa proteins



Recommended Positive Control:
Tonsil, Spleen

Specificity:
This antibody is immunospecific for kappa light chains. They do not react with human lambda light chains.

Application:
For classification of lymphoproliferative disorders.

Staining Procedure:
The prediluted antibody can be used on frozen cryostat sections as well as formalin-fixed paraffin-embedded tissue sections. For paraffin-embedded tissue sections, we recommend an incubation time and temperature of 30 minutes at 37C for this antibody, when used in conjunction with Biømedas immunoperoxidase staining kit. *Prolonged fixation in buffered formalin can destroy the epitope.

Compatibility:
This antibody is compatible with the following Biømeda staining kits: AutoProbe III Wide Spectrum Universal Staining Kits (Cat. No. 08-803, 08-804X), HistoScan Monoclonal Detector (Cat. No. 06-601, 06-601A and 06-601F), Biøstain Super ABC Mouse/Rat (Cat. No. 11-002 and 11-002A), UltraProbe High Sensitivity Staining Kits (Cat. No. 09-900, 09-901, 09-901X).

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Ades et al.	)	Art Unit: 1645
	)	
Application No. 09/613,092	)	Examiner: Devi, S.
	)	
Filing Date: July 10, 2000	)	Confirmation No. 9419
	)	
For: MULTIPLE ANTIGENIC PEPTIDES IMMUNOGENIC AGAINST STREPTOCOCCUS PNEUMONIA	)	

STATEMENT OF COMMON OWNERSHIP/ OBLIGATION OF ASSIGNMENT

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NEEDLE & ROSENBERG, P.C.
Customer Number 23859

Sir:

In accordance with 35 U.S.C. 103(c) and MPEP 706.02(l)(2), the undersigned hereby submits the following statement.

At the time the invention of Application 09/613,092 was made, Application 09/613,092 and U.S. Patent 6,217,884 were owned by The Government of the United States of America as represented by the Secretary, Department of Health and Human Services in c/o Centers for Disease Control and Prevention, as evidenced by assignments recorded at Reel/Frame 011152/0980 and 008262/0001, respectively.

No fee is believed to be due in connection with this Statement, however, if a fee is required, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Gwendolyn D. Spratt
Registration No.

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)

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Gwendolyn D. Spratt — Date: 9-9-04